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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO.  |
|---|-------------|----------------------|---------------------|-------------------|
| 10/079,949  | 02/19/2002  | Ebrahim Zandi        | 13761-7064          | 6542              |
| 7590  | 07/28/2005  |                      |                     |                   |
| Jennifer M. Phelps<br>McCutchen, Doyle, Brown & Enersen, LLP<br>18th Floor<br>Three Embarcadero Center<br>San Francisco, CA 94111 |             |                      | EXAMINER            | PROUTY, REBECCA E |
|   |             |                      | ART UNIT            | PAPER NUMBER      |
|   |             |                      | 1652                |                   |

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                               |                  |  |
|------------------------------|-------------------------------|------------------|--|
| <b>Office Action Summary</b> | Application No.               | Applicant(s)     |  |
|                              | 10/079,949                    | ZANDI ET AL.     |  |
|                              | Examiner<br>Rebecca E. Prouty | Art Unit<br>1652 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 19 April 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-37 and 39-41 is/are pending in the application.
- 4a) Of the above claim(s) 23-37 and 39-41 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-22 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

Claim 38 has been canceled. Claims 1-37, 39-40 and newly presented claim 41 are still at issue and are present for examination.

Applicants' arguments filed on 4/19/05, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Applicants amended claims submitted on 4/19/05 include several inconsistencies in claim numbering. The current claim set includes two claims numbered 21, the first of which (referred to herein as 21A) corresponds to previous claim 21 and the second of which (referred to herein as 21B) appears to be an amended version of previous claim 22. Current claim 22 appears to correspond to previous claim 23. The claims presented as current claims 23-37 are identical to claims 24-38 of the previous claim set. There is no current claim 38 and current claim 41 appears to be a new claim which is improperly labeled as withdrawn and previously amended. Applicants are required in response to this Office Action to submit a new claim set correcting all these inconsistencies.

Claims 23-37 and 39-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a

Art Unit: 1652

nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse the response filed 10/4/04.

Claim 1 is objected to because of the following informalities: Claim 1 is grammatically incorrect in the recitation of "an IKK subunit gene into yeast expression vectors". Appropriate correction is required.

Claim 15 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The recitation of Claim 15 that "wherein said IKK subunit expression is regulated by said promoter" is inherent in the recitation of claim 1 step d. (from which Claim 15 depends) to "controllably inducing the expression of said IKK subunit by means of a promoter".

Claims 4-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is confusing in the recitation "said selectable marker gene encodes leucine histidine, tryptophan, or uracil" as

leucine histidine, tryptophan, and uracil are not encoded by the selectable marker gene. The selection markers in applicants vectors are genes which are involved in the biosynthesis of leucine histidine, tryptophan, and uracil, i.e., the HIS3 gene, the TRP1 gene, the LEU2 gene and the URA3 gene.

Claim 5 (upon which Claim 6 depends) is confusing in the recitation of "said IKK subunits further comprise a polynucleotide encoding a tag" as an IKK subunit is a protein which cannot comprise a polynucleotide. It is suggested that "polynucleotide encoding" be deleted.

Claim 7 (upon which Claims 8 and 9 depend) is confusing in the recitation of "said promoter is an inducible promoter or a constitutive promoter" as Claim 1 (from which Claims 7-9 depend) recites in step d. "controllably **inducing** the expression of said IKK subunit by means of a promoter" [emphasis added] and thus is limited to the use of inducible promoters. Claim 8 is further unclear in the recitation "said inducible promoter is methionine or galactose" as methionine and galactose are not promoters. It is presumed applicants intended "said inducible promoter is induced by methionine or galactose". Claim 9 is further unclear in the recitation "said constitutive promoter is alcohol dehydrogenase" as alcohol dehydrogenase is a protein not a

promoter. It is presumed applicants intended "said constitutive promoter is the alcohol dehydrogenase gene promoter"

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-13, 15, 17-20, and 21B-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Li et al or Rothwarf et al. (Reference C27 of Applicant's PTO-1449) in view of Epinat et al. The rejection is explained in the previous Office Action.

Applicants argue that Li et al. discloses expression of IKK complexes in a mammalian cell system but that studying IKK in mammalian cells is particularly difficult. Applicants further state that "Li et al. was able to only transiently transport and express mammalian cells". Applicants argument that studying IKK

in mammalian cells is particularly difficult is not persuasive because applicants claims are not drawn to methods of studying IKK but are drawn to methods of reconstituting IKK complexes. As such the difficulty of further working with the complexes produced is irrelevant to the instant claims. Li et al. clearly did reconstitute active IKK complexes. Applicants statement that "Li et al. was able to only transiently transport and express mammalian cells" is incomprehensible. One cannot express cells. Assuming that applicants intended this to say that Li et al. was able to only transiently express IKK in mammalian cells, this is not persuasive because Li et al. clearly was successful in producing active IKK complexes as claimed. Applicants have not pointed out any limitation of the instant claims which is not met by Li et al. The examiner clearly addressed the only distinction present (i.e., Li et al. produced the IKK complexes in mammalian cells, applicants claims recite yeast cells) by the addition of Epinat et al. Applicants remaining comments discuss the cited references in piecemeal fashion. However, the rejection is made under 103 over the combination of references. The use of 103 expressly admits that none of the references **alone** expressly meets all limitations of the claims, however, the combination of references clearly does suggest the claimed methods.

Applicants statement that Epinat et al. attempted to reconstitute the complete IKK complex but were unsuccessful is not understood because Epinat et al. were not attempting to reconstitute the IKK complex but the NF- $\kappa$ B/I $\kappa$ B $\alpha$  complex. Epinat et al. was used to provide motivation for the selection of yeast cells as the host cell for the reconstitution of the IKK complex.

Claims 14, 16, and 21A are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al or Rothwarf et al. (Reference C27 of Applicant's PTO-1449) in view of Epinat et al. as applied to claims 1-13, 15, 17-20, and 21B-22 above, and further in view of page 23 of the 1999 Stratgene catalog. The rejection is explained in the previous Office Action. (Note the rejections using Mumberg et al. have been withdrawn as applicants amended claims no longer recite the limitations which Mumberg et al. was cited to address).

Applicant has not presented any arguments specifically traversing this rejection but instead relies upon the traversal discussed above. Therefore, this rejection is maintained for the reasons presented above.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is

reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca E. Prouty whose telephone number is 571-272-0937. The examiner can normally be reached on Tuesday-Friday from 8 AM to 5 PM. The examiner can also be reached on alternate Mondays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The fax phone number for this Group is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on

Application/Control Number: 10/079,949  
Art Unit: 1652

Page 9

access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Rebecca Prouty  
Primary Examiner  
Art Unit 1652